Docket No. 1

#1 - Complaint

10 CA 10849 NG

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA, ET AL. *EX REL.* [UNDER SEAL], Plaintiffs, v. [UNDER SEAL], Defendant.	)	C.A. COMPLAINT

FILED IN CAMERA AND UNDER SEAL

PURSUANT TO THE FALSE CLAIMS ACT, 31 U.S.C. § 3730(b)(2)

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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA, and the STATES of CALIFORNIA, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, LOUISIANA, MASSACHUSETTS, MICHIGAN, MONTANA, NEVADA, NEW HAMPSHIRE, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VIRGINIA, WISCONSIN, the DISTRICT OF COLUMBIA, and DOE STATES 1–26 *EX REL.* [redacted], Plaintiffs, v. ST. JUDE MEDICAL, INC., Defendant.	)	C.A. COMPLAINT FOR VIOLATIONS OF THE FEDERAL FALSE CLAIMS ACT, 31 U.S.C. § 3729 *et seq.*; CALIFORNIA FALSE CLAIMS ACT, Cal. Govt Code § 12650 *et seq.*; CALIFORNIA INSURANCE FRAUDS PREVENTION ACT, Cal. Ins. Code § 1871 *et seq.*; CONNECTICUT FALSE CLAIMS ACT, Conn. Publ. Law 09-05; DELAWARE FALSE CLAIMS AND FALSE REPORTING ACT, 6 Del. C. § 1201 *et seq.*; DISTRICT OF COLUMBIA PROCUREMENT REFORM AMENDMENT ACT, D.C. Code Ann. §§ 1-1188.13 *et seq.*; FLORIDA FALSE CLAIMS ACT, Fla. Stat. Ann. § 68.081 *et seq.*; GEORGIA FALSE MEDICAID CLAIMS ACT, Ga. Code Ann. § 49-4-168 *et seq.*; HAWAII FALSE CLAIMS ACT, Haw. Rev. Stat. § 661-21 *et seq.*; ILLINOIS

WHISTLEBLOWER REWARD AND PROTECTION ACT, 740 Ill. Comp. Stat. § 175/1-8; ILLINOIS INSURANCE CLAIMS FRAUD PREVENTION ACT, 740 Ill. Comp. Stat. § 92; INDIANA FALSE CLAIMS AND WHISTLEBLOWER PROTECTION ACT, Ind. Code § 5-11-5.5 *et seq.*; LOUISIANA MEDICAL ASSISTANCE PROGRAMS INTEGRITY LAW, La. Rev. Stat. § 437 *et seq.*; MASSACHUSETTS FALSE CLAIMS LAW, Mass. Gen. Laws ch. 12 § 5 *et seq.*; MICHIGAN MEDICAID FALSE CLAIMS ACT, Mich. Comp. Laws § 400.601 *et seq.*; MONTANA FALSE CLAIMS ACT, Mont. Code Ann. § 17-8-401 *et seq.*; NEVADA FALSE CLAIMS ACT, Nev. Rev. Stat. Ann. § 357.010 *et seq.*; NEW HAMPSHIRE FALSE CLAIMS ACT, N.H. Rev. Stat. Ann. § 167:61 *et seq.*; NEW JERSEY FALSE CLAIMS ACT, N.J. Stat. § 2A:32C-1 *et seq.*; NEW MEXICO MEDICAID FALSE CLAIMS ACT and NEW MEXICO FRAUD AGAINST TAXPAYERS ACT, N.M. Stat. Ann. § 27-14-1 *et seq.* and N.M. Stat. Ann. § 44-9-1 *et seq.*; NEW YORK FALSE CLAIMS ACT, N.Y. State Fin. § 187 *et seq.*; NORTH CAROLINA FALSE CLAIMS ACT, N.C. Gen. Stat. § 1-605 et seq.; OKLAHOMA MEDICAID FALSE CLAIMS ACT, 63 Okl. St. § 5053 *et seq.*; RHODE ISLAND FALSE CLAIMS ACT, R.I. Gen. Laws § 9-1.1-1 *et seq.*; TENNESSEE FALSE CLAIMS ACT and TENNESSEE MEDICAID FALSE CLAIMS ACT, Tenn. Code Ann. §§ 4-18-101 *et seq.* and 71-5-181 *et seq.*; TEXAS MEDICAID FRAUD PREVENTION LAW, Tex. Hum. Res. Code Ann. § 36.001 *et seq.*; VIRGINIA FRAUD AGAINST TAXPAYERS ACT, Va. Code Ann. §§ 8.01-216.1 *et seq.*; and, WISCONSIN FALSE CLAIMS FOR MEDICAL ASSISTANCE ACT, Wis. Stat § 20.931 *et seq.*

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JURY TRIAL DEMANDED

1. *Qui tam* plaintiff [redacted], on behalf of the United States, the States of California, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Massachusetts, Michigan, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Virginia, Wisconsin, the District of Columbia, and Doe States 1–26 (collectively "the States"), for [redacted] Complaint against defendant St. Jude Medical, Inc. ("St. Jude" or "defendant"), alleges as follows.

Introduction

2. This is an action to recover damages and civil penalties on behalf of the United States of America and the States arising from false and/or fraudulent records, statements and

claims made, used and caused to be made, used or presented by defendant and/or its agents, employees and co-conspirators, in violation of the Federal Civil False Claims Act, 31 U.S.C. §§ 3729–33, as amended ("the FCA" or "the Act"), and the false claims acts of the States as set forth below.

3. Defendant St. Jude Medical, Inc. manufactures and sells medical devices worldwide. Two of St. Jude's primary products are pacemakers and implantable cardioverter defibrillators ("ICDs"). Pacemakers and ICDs are small electrical devices that are implanted in the patient's chest to regulate heart rhythm and, in the case of ICDs, deliver shocks to correct rhythm abnormalities. This case concerns St. Jude's marketing and sale of a flawed software feature in its pacemakers and ICDs. The feature, called the "QuickOpt," has no proven utility and was approved by the FDA based on research results that St. Jude knew, or should have known, were scientifically unsound. As detailed below, use of QuickOpt may cause patients harm and possibly death.

4. The QuickOpt feature relates to the use of pacemakers and ICDs to treat heart failure. Heart failure is a chronic condition in which the heart can no longer pump enough blood to meet the body's needs. Among its many serious consequences, heart failure can distort the heart's normal contraction pattern and cause it to beat inefficiently. For patients with this condition, a biventricular pacemaker or ICD may restore a more normal contraction pattern and thus improve cardiac performance. This type of treatment is known as cardiac resynchronization therapy ("CRT").

5. The challenge for doctors, however, is to determine what "pacing intervals" the pacemaker or ICD should deliver. Pacing intervals are measurements of the time that elapse between the beats (naturally occurring or paced) in the various chambers of the heart. "Pacing

optimization" is a procedure by which the doctor determines the best pacing intervals for the patient. In general, optimization methods require the doctor to test various pace settings (using the pacemaker or ICD) on the patient in a lab, and then measure the patient's heart performance at each setting. The doctor then programs the setting that corresponds to the best performance measurement. This is a slow process and requires highly skilled specialists. Because of the time and expense involved, traditional optimization methods are unpopular with doctors, who are typically reimbursed for the procedure on a modest flat rate basis, and the procedure is rarely performed, despite the potential benefits to the patient.

6. St. Jude designed a feature to make optimization easier and quicker to perform than traditional optimization, which therefore made it more profitable for health care providers. Marketed as "QuickOpt," the software feature is designed to replace traditional test-and-measure optimization methods with an automated, one-step process.

7. The QuickOpt purports to do in two minutes and with one push of a button what traditionally has taken doctors at least 30 minutes or longer to perform through traditional optimization techniques. But like many devices that promise miracle results with "one simple step" and no effort, St. Jude's claims about the effectiveness of QuickOpt are built on smoke and mirrors. At bottom there is no evidence that it works, and St. Jude conceals this fact from the medical community in a number of misleading and fraudulent ways described below. Even worse than being ineffective, however, the QuickOpt may cause harm to those patients who rely upon it and forego traditional, proven optimization techniques.

8. St. Jude markets QuickOpt as software for its pacemaker/ICD "programmers." Programmers are computers that doctors use to wirelessly retrieve data from implanted devices and program the devices with new settings. As discussed below, at the press of a button

QuickOpt will retrieve the pacemaker/ICD's current pace settings, compute suggested "optimum" settings, and display the current and proposed settings on the programmer screen. The doctor can either keep the old settings or accept QuickOpt's "optimum" settings.

9. Unlike traditional test-and-measure optimization, however, QuickOpt's "optimum" settings are merely a *prediction* of which settings could work best for the patient. QuickOpt does not (and indeed cannot) measure the effect of its settings on the patient's heart performance, which is the only way to know if the settings are truly optimal. QuickOpt's algorithm is supposedly capable of identifying which settings will yield the best performance, without performance measurements. To persuade doctors and the FDA that it works, St. Jude sponsored a clinical study to attempt to show that that the settings QuickOpt predicts are consistent with the settings a doctor would identify as "optimal" using a traditional optimization method.

10. As will be detailed below, the clinical study was deeply flawed. The authors of the study manipulated the study's design to produce the *appearance* of a successful outcome when one truly did not exist. They then made no attempt to check their work by comparing their data against a negative "control," such as default intervals or randomly selected intervals. Had they checked, their results would have been exposed as inconclusive. That the authors abandoned reliable scientific methodology in favor of a methodology that ensured a positive outcome is unsurprising: St. Jude paid for the study and each of the authors had a prior relationship with the company. With the deceptive study in hand, St. Jude passed through the FDA approval process behind a veneer of scientific evidence. After approval, St. Jude falsely promoted the study to doctors as proof that QuickOpt, its "one-touch" optimization method, was safe and effective for their patients.

11. The clinical study, therefore, misled doctors and the FDA into believing that QuickOpt is a valid optimization method. This misconception is profoundly dangerous because there is no evidence that QuickOpt is any better at identifying a patient's optimum pacing intervals than settings chosen at random. Absent any evidence that QuickOpt works, patients that use it are at tremendous risk of harm. Badly chosen settings not only fail to optimize the patient's heart performance, but can negate the value of CRT entirely, and in doing so can increase the risk of death and significant illness. Recent studies have suggested that QuickOpt is not only unproven but ineffective. Ineffective optimization increases the risk of morbidity and mortality in CRT patients.

[redacted]

13. St. Jude continues to market and distribute QuickOpt even though it knowingly lacks any empirical proof that it works. St. Jude also continues to promote the flawed clinical study as establishing QuickOpt's effectiveness—when it knows the study is valueless. In short, St. Jude is fraudulently marketing the QuickOpt feature to doctors as being "clinically proven," when in fact it is not. On the basis of these and other false representations, doctors are currently

using QuickOpt to modify their patients' heart rhythms, and billing federal and state health care programs for the "enhanced" pacemakers and ICDs and the clinically unproven procedures.

14. Government health care entitlement programs, such as Medicare and Medicaid, have paid large sums for QuickOpt pacemakers, ICDs, and procedures that St. Jude knew had no known positive effect on any medical condition. Because Medicare and Medicaid only reimburse for procedures that are medically necessary, St. Jude has caused a large number of false claims to be submitted to the federal and state governments. Every reimbursement request or other claim for payment, knowingly submitted for a QuickOpt procedure, violates the Federal False Claims Act ("FCA") and the FCA's state-law counterparts.

15. The FCA was originally enacted during the Civil War, and was substantially amended in 1986 and in 2009. Congress enacted these amendments to enhance and modernize the government's tools for recovering losses sustained by frauds against it after finding that federal program fraud was pervasive. The amendments were intended to create incentives for individuals with knowledge of fraud against the government to disclose the information without fear of reprisals or government inaction, and to encourage the private bar to commit resources to prosecuting fraud on the government's behalf.

16. The FCA provides that any person who presents or causes to be presented false or fraudulent claims for payment or approval to the United States Government, or knowingly makes, uses, or causes to be made or used false records and statements to induce the United States to pay or approve false and fraudulent claims, is liable for a civil penalty of up to $11,000 for each such claim, plus three times the amount of the damages sustained by the federal government.

17. The FCA allows any person having information about false or fraudulent claims to bring an action on behalf of the government, and to share in any recovery. The FCA requires that the complaint be filed under seal for a minimum of 60 days (without service on the defendant during that time) to enable the United States to (a) conduct its own investigation without the defendant's knowledge, and (b) determine whether to join the action.

18. As set forth below, defendant's actions alleged in this Complaint also constitute violations of the California False Claims Act, Cal. Govt Code § 12650 *et seq.*; the California Insurance Frauds Prevention Act, Cal. Ins. Code § 1871 *et seq.*; the Connecticut False Claims Act, Conn. Publ. Law 09-05; the Delaware False Claims and False Reporting Act, 6 Del. C. § 1201 *et seq.*; the District of Columbia Procurement Reform Amendment Act, D.C. Code Ann. §§ 1-1188.13 *et seq.*; the Florida False Claims Act, Fla. Stat. Ann. § 68.081 *et seq.*; the Georgia False Medicaid Claims Act, Ga. Code Ann. § 49-4-168 *et seq.*; the Hawaii False Claims Act, Haw. Rev. Stat. § 661-21 *et seq.*; the Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. § 175/1-8; the Illinois Insurance Claims Fraud Prevention Act, 740 Ill. Comp. Stat. § 92; the Indiana False Claims and Whistleblower Protection Act, Ind. Code § 5-11-5.5 *et seq.*; the Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. § 437 *et seq.*; the Massachusetts False Claims Law, Mass. Gen. Laws ch. 12 § 5 *et seq.*; the Michigan Medicaid False Claims Act, Mich. Comp. Laws § 400.601 *et seq.*; the Montana False Claims Act, Mont. Code Ann. § 17-8-401 *et seq.*; the Nevada False Claims Act, Nev. Rev. Stat. Ann. § 357.010 *et seq.*; the New Hampshire False Claims Act, N.H. Rev. Stat. Ann. § 167:61 *et seq.*; the New Jersey False Claims Act, N.J. Stat. § 2A:32C-1 *et seq.*; the New Mexico Medicaid False Claims Act and the New Mexico Fraud Against Taxpayers Act, N.M. Stat. Ann. § 27-14-1 *et seq.* and N.M. Stat. Ann. § 44-9-1 *et seq.*; the New York False Claims Act, N.Y. State Fin. § 187 *et seq.*;

the North Carolina False Claims Act, N.C. Gen. Stat. § 1-605 et seq.; the Oklahoma Medicaid False Claims Act, 63 Okl. St. § 5053 *et seq.*; the Rhode Island False Claims Act, R.I. Gen. Laws § 9-1.1-1 *et seq.*; the Tennessee False Claims Act and Tennessee Medicaid False Claims Act, Tenn. Code Ann. §§ 4-18-101 *et seq.* and 71-5-181 *et seq.*; the Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code Ann. § 36.001 *et seq.*; the Virginia Fraud Against Taxpayers Act, Va. Code Ann. §§ 8.01-216.1 *et seq.*; and the Wisconsin False Claims for Medical Assistance Act, Wis. Stat § 20.931 *et seq.*

19. Based on these provisions, *qui tam* plaintiff and relator [redacted] seeks to recover all available damages, civil penalties, and other relief for federal and state violations alleged herein, in every jurisdiction to which defendant's misconduct has extended.

I. PARTIES

A. Plaintiffs

20. *Qui tam* plaintiff [redacted] ("Relator") [redacted]

21. [redacted]

[redacted]

23. [redacted]

24. The governmental plaintiffs in this lawsuit are the United States and the States of California, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Massachusetts, Michigan, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Virginia, Wisconsin, the District of Columbia, and Doe States 1–26 (collectively "the States").

25. Plaintiffs Doe States 1–26 consist of the States that subsequent to the filing of this Complaint enact false claims act statutes that permit *qui tam* lawsuits, including but not limited to the States of Alabama, Alaska, Arizona, Arkansas, Colorado, Idaho, Iowa, Kansas, Kentucky,

Maine, Maryland, Minnesota, Mississippi, Missouri, Nebraska, North Dakota, Ohio, Oregon, Pennsylvania, South Carolina, South Dakota, Utah, Vermont, Washington, West Virginia, and Wyoming.

B. Defendant

26. Defendant St. Jude Medical, Inc. is a Delaware Corporation with its headquarters in St. Paul, Minnesota. St. Jude develops, manufactures, and sells medical devices worldwide. St. Jude has four "operating segments": CRM, which makes cardiac pacing devices such as pacemakers and internal cardioverter defibrillators, Cardiovascular ("CV"), which makes heart valves and cardiac surgery therapy devices, Atrial Fibrillation ("AF"), which makes electrophysiology catheters and mapping/navigation systems, and Neuromodulation ("Neuro"), which makes neurostimulation devices. CRM is St. Jude's largest operating segment by far, with more than three times the net sales of the next largest operating segment. CRM's net sales in 2008 totaled $2.7 billion, or 61.9% of St. Jude's total net sales. The CRM division is headquartered in Sylmar, California.

II. JURISDICTION AND VENUE

27. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and 31 U.S.C. § 3732(a), which specifically confers jurisdiction on this Court for actions brought under 31 U.S.C. § 3730.

28. This Court has supplemental jurisdiction, pursuant to 28 U.S.C. § 1367, over the Relator's state law claims, as those claims and the Relator's federal law claims are sufficiently related to form part of the same case or controversy under Article III of the United States Constitution. This Court has express supplemental jurisdiction over the States' claims pursuant to 31 U.S.C. § 3732(b), as the States' claims arise from the same transactions and occurrences as the federal action.

29. This Court has personal jurisdiction over St. Jude, pursuant to 31 U.S.C. § 3732(a), as St. Jude can be found in, resides in, transacts business in, and has committed acts related to the allegations in this Complaint in the District of Massachusetts.

30. Venue is proper, pursuant to 31 U.S.C. § 3732(a) and 28 U.S.C. § 1391(b)–(c), as St. Jude can be found in, resides in, and/or transacts business in the District of Massachusetts, and because many of the violations of 31 U.S.C. § 3729 discussed herein occurred within this judicial district.

III. APPLICABLE LAW

A. Government Health Care Programs Only Reimburse Medically Necessary Treatments and Services

31. To participate in the Medicare and Medicaid programs, providers are obligated to submit claims for reimbursement *only* for "reasonable and necessary medical services." 42 U.S.C. § 1395y(a)(1)(A). When performing a procedure reimbursable by Medicare or Medicaid, providers must assure that their services are provided "economically and only when, and to the extent, medically necessary." 42 U.S.C. § 1320c-5(a). Furthermore, in performing a reimbursable procedure, a provider must assure that the service will be supported by evidence showing that it was medically necessary. 42 U.S.C. § 1320c-5(a)(3).

32. When presenting a claim for reimbursement to Medicare or Medicaid, the provider must certify that the service provided was medically necessary. 42 U.S.C. § 1395n(a)(2)(8).

B. The Promotion and Sale of Defective and Misbranded Medical Devices is Prohibited

33. QuickOpt is a medical device within the meaning of the Food, Drug, and Cosmetic Act ("FDCA"). The FDCA defines a medical device to be, in part, "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related

article, including any component, part, or accessory, which is . . . intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease in man or other animals. . . ." FDCA § 201(h); 21 U.S.C. § 321(h). As a medical device, QuickOpt is subject to federal laws and FDA regulations on its approval, sale, and marketing.

34. A medical device is misbranded if its labeling is false or misleading. FDCA § 502(a); 21 U.S.C. § 352(a). As will be discussed herein, St. Jude's specifications for numerous pacemakers and ICD/CRT-Ds represent that QuickOpt provides effective AV and V-V optimization without the need for echocardiography-guided optimization. In fact, St. Jude has long known that the evidence underpinning this assertion was not credible, and that it had no valid proof that QuickOpt's "optimized" timing was any better than a randomly selected interval.

35. A medical device is also misbranded if it is hazardous to patient health when used as directed in its labeling. FDCA § 502(j); 21 U.S.C. § 352(j). Because the pacing interval has a demonstrable effect on cardiac performance, a device is a hazard to patients' health if it provides an interval that is worse than the CRT device's "default" interval—the default being the best interval for an average patient.

36. The FDCA prohibits the introduction of misbranded medical devices into interstate commerce. FDCA § 301(a); 21 U.S.C. § 331(a). Likewise, misbranded devices may not be sold after interstate shipment of the device, or a device component. FDCA § 301(k); 21 U.S.C. § 331(k); *see* FDCA § 303; 21 U.S.C. § 333 (imposing penalties).

37. The FDCA also prohibits the advertising of medical devices that is false or misleading in any way. FDCA §§ 502(q)(1), (r); 21 U.S.C. §§ 352(q)(1), (r).

38. With the exception of certain investigational devices not at issue in this case, medical devices must be approved by the FDA in order to qualify for Medicare coverage.

Medicare Benefit Policy Manual, Ch. 14, § 10. Medicare does not cover services related to a non-covered medical device. *Id.* at § 80.

IV. THE QUICKOPT ALGORITHM

A. Purpose, Design, and Operation

39. St. Jude created QuickOpt to be a quicker alternative to existing optimization techniques and therefore more profitable to the performing doctor, who is typically reimbursed for the procedure on a flat rate basis. QuickOpt is intended to reach the same outcome as Doppler echocardiography, an accepted but time-consuming optimization technique, but reach it faster and automatically. Indeed, St. Jude promotes QuickOpt as a "one touch" procedure, easily performed by selecting a few options on the computer screen of the CRT device's programmer. Because QuickOpt can be performed in less than two minutes during routine office visits, and requires no extra equipment or lab space, it is a lucrative procedure for physicians who can earn $85–$100 for two minutes' work, not thirty or more.

40. From St. Jude's perspective, the QuickOpt feature is a valuable way to distinguish its CRT devices from those of its two larger competitors, Boston Scientific and Medtronic. Pacemakers and ICDs are now commodity products that offer the same basic performance and functionality. Manufacturers like St. Jude therefore compete in part by adding extra features to their devices, much as car manufacturers compete by adding extra details, like airbags and stereos, to their cars. In the case of QuickOpt, St. Jude's sales strategy was to bundle the software for free with its pacemaker/ICD programmers, in the hope of improving its market share for the underlying devices.

41. Many physicians have chosen St. Jude's pacemakers and ICDs for their patients because of the QuickOpt feature, due to its ease and speed of use and St. Jude's representations as to its accuracy in setting the optimal pacing interval.

1. The Design of the QuickOpt Algorithm

42. As discussed above, pacing optimization is a procedure that adjusts pacing intervals in order to improve the heart's efficiency and increase the amount of blood it is able to circulate. *See supra* ¶¶4–5. The pacing treatment of heart failure is known as cardiac resynchronization therapy ("CRT"). CRT can be used in heart failure patients who have a normal heart rhythm but uncoordinated and mechanically inefficient contraction patterns (described below), or in patients who have heart rhythms that are abnormally slow and potentially dangerous. The treating physician can control the heart's contraction pattern by adjusting parameters called pacing intervals, or delays.

43. Pacing intervals are measurements of the time that elapses between the heart's contractions. For optimization, three intervals are important: the sensed atrio-ventricular ("AV") delay, the paced AV delay, and the interventricular ("V-V") interval. The sensed AV delay is the time that elapses between detection (or "sensing") of electrical activity in the atrium (which indicates the occurrence of a spontaneous atrial contraction) and delivery of a ventricular pace. The paced AV delay is the time between delivery of an atrial pace (which results in a pacemaker-induced atrial beat) and delivery of a ventricular pace. The term "AV delay" is frequently used in the general sense to refer to either or both the sensed and/or paced AV delay with the understanding that for an individual patient both the sensed and paced AV delays must be specified. V-V interval is the delay between the delivery of paces to the heart's right and left ventricles. These intervals, along with others, govern the heart's contraction pattern. Pacing intervals have an acute effect on the heart's performance, and optimizing these parameters is believed to lead to improved clinical outcomes for patients over the long term. The process of optimization, therefore, is to identify the best AV delays and V-V interval (collectively, "AV and

V-V delays") for each patient, and then program those intervals into the patient's pacemaker or ICD (often called a "CRT device").

44. QuickOpt is an algorithm that purports to identify the optimal AV and V-V delays in people with implanted St. Jude CRT devices.

45. QuickOpt predicts optimal AV and V-V delays using intracardiac electrogram ("IEGM") signals. An IEGM is a recording of the heart's electrical activity, taken from within the heart. CRT devices record IEGM signals via the electrical leads that connect the device to the heart.

46. QuickOpt's basic postulate is that optimum pacing can be inferred from the heart's electrical conduction patterns, as opposed to a direct measurement of the heart's hemodynamic performance using a tool, such as an echocardiograph, that measures the volume of blood the heart displaces. The algorithm uses IEGM signals to derive information about the heart's timing. QuickOpt's predictions, however, are based on unproven assumptions about optimal pacing. For example, the algorithm's premise for optimizing V-V delay is that optimum pacing should minimize a certain variable: the electrical activation time of the left ventricle. St. Jude has offered no empirical evidence to support this premise, or to support the mathematical derivations, which also rely on a number of implicit assumptions, that it used to incorporate the premise into the QuickOpt algorithm. Nevertheless, based on these assumptions and derivations, QuickOpt claims to be able to predict optimum V-V intervals. Prediction of optimum AV delays is similarly based on theoretical assumptions—that the ventricles should not be paced until 30 or 60 milliseconds after the end of atrial activity. Though the authors of St. Jude-sponsored research articles supporting QuickOpt claim that the algorithm for AV delay is an "empirical

method" based on "clinical observation," they do not report what their supposed clinical observations were, nor do they cite to any original sources.

47. It is important to emphasize that the QuickOpt algorithm does not optimize the heart's performance, *i.e.*, the volume of blood the heart can pump. QuickOpt only *predicts the AV and V-V delays that, based on multiple theoretical assumptions, should correspond to optimal performance*. The only way to actually know if the heart's hemodynamic performance has been optimized is to measure hemodynamic performance *directly*.

48. Doppler echocardiography-based optimization is an example of direct measurement. The physician tests different AV and V-V delays on the patient. The physician analyzes the effect each delay has on the heart by using echocardiography to measure the heart's hemodynamic performance. The AV and V-V delays that yield the best hemodynamic performance, as measured by echocardiography, can generally be considered optimal.

49. To save time, QuickOpt dispenses with any confirmatory performance measurement like echocardiography. Instead, St. Jude claims that its algorithm will predict with 96 percent accuracy the same AV and V-V delays as those determined by echocardiography. As explained below, this is a spurious correlation. Nonetheless, based on this claim, St. Jude asserts that physicians no longer need to laboriously compare AV and V-V delays against hemodynamic performance—St. Jude claims that QuickOpt will reach the same result as echocardiography automatically. This claim is false.

2. Physician Operation of QuickOpt to "Optimize" Pacing

50. St. Jude incorporated the QuickOpt algorithm as a featured tool in its CRT device programmers. A programmer is a computer that physicians use to download information from and to set the programmable parameters of implanted pacemakers and ICDs. The programmer is attached by a cord to a magnetic telemetry wand, which transmits and receives data wirelessly to

and from the device implanted in the patient's chest. To communicate with the implanted device, the physician places the wand over the patient's chest. Once in contact, the physician can use the programmer to retrieve data on the patient's heart rhythm, monitor heart rhythm data in real time, and program new settings into the device. Some modern programmers can also communicate with the implanted device remotely, using radio technology rather than the magnetic telemetry wand.

51. The QuickOpt program has two features: an "Optimization Wizard" and a "Manual Test." The Wizard automatically measures the heart's electrical signals—which are transmitted to the programmer from the implanted CRT device—with pre-set test parameters, and then calculates the supposedly optimal AV and V-V delay settings. The Wizard begins by sequentially measuring a number of timing events from the intracardiac leads. Once the events are measured, the Wizard displays programmed settings (*i.e.*, those currently being used) and "optimum" settings for AV delay and V-V delay. This process takes less than two minutes. The Wizard then displays a check mark if the programmed setting is different from QuickOpt's predicted optimum setting.

52. The Wizard then gives the programming physician three options. First, a "Program Optimum Values" button will program every setting to its QuickOpt-suggested optimum, and conclude the test. By hitting the button, the physician accepts QuickOpt's settings wholesale. Second, the physician can accept some QuickOpt suggestions and reject others by un-checking individual check marks. Third, the physician can reject all QuickOpt suggestions, leaving all parameters unchanged.

53. The Manual Test allows the physician to conduct the same measurements manually. The physician can choose different test settings, and view detailed measurement

results. At the conclusion of every test, however, QuickOpt displays its suggested optimum setting. As with the Wizard, the physician can accept or reject QuickOpt's setting.

54. If the physician accepts QuickOpt's "optimal" setting, the programmer will program the setting into the patient's implanted device. The patient's CRT device will pace the heart at the new, QuickOpt-determined intervals, until the physician next reprograms it.

55. Unlike traditional optimization methods, which allow the doctor to test multiple settings and see which ones the patient responds to best, QuickOpt does not provide a way for doctors to review whether its proposed settings are good or bad for the patient. By displaying only the current and suggested delay settings (which cannot be meaningfully compared), QuickOpt eliminates the doctor's role in performing optimization. Doctors who use QuickOpt simply have to trust that it works. This fact makes the clinical evidence underpinning QuickOpt particularly important, because it is the source doctors have for evaluating the device.

56. To understand the consequences of choosing QuickOpt's "optimal" settings, one must recognize the importance of the default CRT device settings that QuickOpt replaces. All CRT devices come preprogrammed with default AV delay and V-V interval settings. The settings manufacturers choose as their defaults are ones that clinical studies have shown to be the best for patients on average. The default settings are thus proven to be safe and effective, even if they are not necessarily the best choice for every patient. As will be discussed herein, QuickOpt replaces these safe and effective settings with "optima" that have not been proven to be any better than randomly chosen settings. Using QuickOpt, therefore, risks a worse clinical response than the patient would have had with default settings, or even negating the value of CRT entirely.

B. FDA Approved QuickOpt, a Class III Device, on the Basis of Grossly Misleading Clinical Trial Data

1. Regulatory Background of the FDA Approval Process for Class III Medical Devices

57. The FDA categorizes medical devices into one of three classes, I–III, depending on the level of regulatory control needed to ensure the device's safety and efficacy. Unless an exemption applies, the FDA does not allow manufacturers to market a medical device without submitting an application or submission to the FDA in advance. The class of the particular device determines the nature of the necessary premarket application or submission. Class III devices are subject to the greatest controls. A device is in class III if it supports or sustains life, is substantially important to preventing impairment of human health, or presents an unreasonable risk of illness or injury, and if general controls (such as those applied to classes I and II) may not reasonably assure its safety. 21 C.F.R. § 860.3(c)(3).

58. Class III devices must receive FDA approval before they can be marketed to the public. The device maker must submit a premarket approval application ("PMA") to the FDA. The PMA must contain a number of elements, such as a summary of the overall application, a complete description of the proposed device, the technical results of non-clinical and clinical studies, and a device sample.

59. The PMA must include detailed information about any clinical studies performed on the device. Broadly stated, the FDA wants to know all the material information about each study, including:

> [R]esults of the clinical investigations involving human subjects with the device including clinical protocols, number of investigators and subjects per investigator, subject selection and exclusion criteria, study population, study period, safety and effectiveness data, adverse reactions and complications, patient discontinuation, patient complaints, device failures and replacements, tabulations of data from all individual subject report

> forms and copies of such forms for each subject who died during a clinical investigation or who did not complete the investigation, results of statistical analyses of the clinical investigations, device failures and replacements, contraindications and precautions for use of the device, and any other appropriate information from the clinical investigations.

21 C.F.R. § 814.20(b)(6)(ii). In addition to information on clinical investigations, the FDA also requires a bibliography of all published reports "whether adverse or supportive, known to or that should reasonably be known to the applicant and that concern the safety and effectiveness of the device." § 814.20(b)(8)(i).

60. When a device manufacturer wants to make a change that affects the safety or effectiveness of a medical device for which the manufacturer has an approved PMA, it must submit a PMA supplement. *See* 21 C.F.R. § 814.39. The PMA supplement generally must contain the same types of information as a PMA, such as the results of clinical studies. § 814.39(c).

61. Clinical studies that underpin PMA and PMA supplements—*i.e.*, studies performed on hazardous, unapproved devices—must receive a separate approval by the FDA before they can be performed. This early approval, called an investigational device exemption ("IDE"), predates the PMA or PMA supplement, and allows the clinical study's investigators to test the investigational device on human subjects in order to acquire the safety and effectiveness data required to support the PMA or PMA supplement. 21 C.F.R. §§ 812.1–.150.

2. FDA Approved QuickOpt, a Class III Device, on the Basis of a PMA Supplement

62. Because QuickOpt was a new feature for St. Jude's existing line of CRT devices, and not a stand-alone product, the approval St. Jude sought from the FDA was not for a new product (a PMA), but for an addition to approved CRT devices that affected their safety and effectiveness (PMA supplements). Therefore, on or about February 16–17, 2006, St. Jude filed a

PMA supplement for every CRT device to which it wanted to add QuickOpt. Though these PMA supplements were for nine different CRT devices, the devices all shared the same programmers. Therefore, the PMA supplements all sought the same change: "[a]pproval for the modifications to the programmer software, model 3307 v6. 1. 1c and model 3330 v4. 1. 1, to include the quickopt timing cycle feature."

63. FDA approved QuickOpt on July 28, 2006. Upon information and belief, the FDA's approval was based in large part on the study described immediately below.

3. St. Jude Sponsored a Deeply Flawed Clinical Study to Evaluate the Safety and Effectiveness of QuickOpt

64. To gather the safety and efficacy data needed to support the PMA supplements, St. Jude sponsored a clinical study of the QuickOpt algorithm, pursuant to an IDE granted by the FDA. The study was conducted by a team of researchers led by James Porterfield, M.D., and published in a medical journal, with James H. Baker II, M.D. serving as lead author. This Complaint will refer to the study as the "Baker study."

65. St. Jude's influence on the Baker study was significant. St. Jude's CRM Division sponsored the Baker study, and each of the researchers involved in it had prior, and often longstanding, affiliations with St. Jude. Dr. Baker, for example, has authored numerous St. Jude-sponsored studies and presently serves on a St. Jude medical advisory board.

66. The Baker study suffers from two basic flaws that render its conclusions meaningless: (1) it failed to compare QuickOpt's predicted pacing intervals directly to the optimum pacing intervals measured through the reference method, even though that comparison is the only way to evaluate QuickOpt's effectiveness, and instead compared them against a common variable that will produce a misleading near-perfect correlation every time, and (2) it failed to use proper controls to test the accuracy of the results.

67. The Baker study's hypothesis was that optimization with QuickOpt would identify similar pacing intervals as traditional Doppler echocardiograph optimization (the reference method). For unexplained reasons, however, the Baker study did not compare the optimum delay identified by QuickOpt and the optimum delay identified by Doppler echocardiography directly, even though this was the comparison it was supposedly making.

68. Instead, the Baker study compared a performance metric called aortic velocity time integral ("AVTI"), which is proportional to the heart's stroke volume, *i.e.*, the amount of blood ejected from the ventricle with each heart beat. The researchers used Doppler echocardiography to measure AVTI at different test delays and then, in a bizarre analysis, rather than comparing the QuickOpt-predicted optimum delay to the optimum delay determined by AVTI, they compared the best AVTI measurement over all test delays to the AVTI associated with the QuickOpt-predicted optimum delay.

69. For paced AV delay, the Baker study reported a 97.5 percent correlation between the best AVTI measurement (as taken by Doppler echocardiogram) and the AVTI associated with QuickOpt's optimum delay. For sensed AV delay, the correlation was 96.1 percent. For V-V delay, the correlation was 96.6 percent. Given these near-perfect matches, the researchers concluded that "a strong concordance between the IEGM method [*i.e.*, QuickOpt] and echocardiogram optimization was consistently observed in all analyses. The automated programmer-based IEGM method provides comparable results to echocardiogram optimized [paced AV, sensed AV,] and VV delay settings in patients with ICDs and CRT-D devices."

70. The Baker study, however, did not compare QuickOpt's predictions against Doppler echocardiography's optimum delays. Instead, it compared the *AVTI* associated with QuickOpt's predictions to Doppler echocardiography's optimal *AVTI*. The real (and

commonsense) test of whether QuickOpt is safe and effective—whether or not QuickOpt's optimum *delays* correspond to Doppler echocardiography's optimum *delays*—went entirely unaddressed.

71. The Baker study, therefore, introduced a variable (AVTI) in between its two points of comparison, the delays. AVTI, however, is not a proxy for the delays, because it will yield a high correlation even when the delays are actually different. This flawed approach would have been easily exposed had the study properly tested the evidence against a control. But the Baker study also failed to use negative controls, which are values known to produce a negative result, and which are used in basic scientific research to reveal false positives.

72. As mentioned above, the Baker study simply compared the best AVTI measured by Doppler echocardiography to the AVTI associated with QuickOpt's "optimal" delay. To prove that QuickOpt's predicted delays are an improvement over default values, however, the Baker study needed to also compare the AVTI associated with QuickOpt's "optimum" delay against AVTI values associated with *default* pacing intervals. If QuickOpt were actually identifying the best delays for every patient, or even improved delays compared to default settings, then QuickOpt's results would be consistently better than those associated with the control sample's default delays. The Baker study, however, failed to test this. Furthermore, the Baker study also failed to address whether QuickOpt's "optimum" intervals offer better performance than randomly selected intervals. By not repeating the analysis using negative controls (default delays and randomly selected delays) it is impossible to tell whether the strong correlation they report is due to the performance of QuickOpt or anomalies in the test procedure as described above. It is also impossible to tell whether QuickOpt performs better than either

default settings or randomly selected intervals. [redacted]

[redacted].

73. The Baker study's flaws can be explained by analogy to a lie detector test. In administering a polygraph test, the police would not test the polygraph's ability to detect lies by only asking for answers they know to be false. Nor would police perform such a test by comparing the worst lie told against the polygraph's largest recorded "event." Neither of these "tests" would show whether the lie detector is functioning properly—*i.e.*, separating truths from lies. Instead, to know if the lie detector works or not, the police would ask for both answers they know are true, and answers they know are false. Only if the polygraph ignores the true answers, and identifies the false ones, could the police conclude it is accurate.

74. Thus, because the Baker study failed to compare QuickOpt's predicted pacing intervals to pacing intervals determined through accepted methods, and because it also failed to test QuickOpt's predicted intervals against negative controls, its conclusions are misleading and completely uninterpretable.

4. FDA Approved QuickOpt on the Basis of the Baker Study

75. St. Jude submitted the Baker study to the FDA as the principal clinical evidence underpinning its QuickOpt PMA supplements. The study's flaws went unnoticed, and the FDA approved QuickOpt on July 28, 2006. St. Jude began marketing QuickOpt to cardiologists and hospitals immediately thereafter. As the only premarket study conducted under an FDA-approved IDE, the Baker study was integral to the FDA's decision to approve QuickOpt.

V. FRAUD ON THE GOVERNMENT

76. [redacted]

[redacted]. Nevertheless, St. Jude continues to market QuickOpt on the basis of the Baker study, even though it knows the study is not creditable. To knowingly market QuickOpt in these circumstances—on the basis of sham science—is no better than selling snake oil.

77. Furthermore, by knowingly marketing an unproven medical device, St. Jude has contravened and frustrated the purpose and design of the Food, Drug, and Cosmetic Act. The government health care entitlement programs, Medicare and Medicaid, have paid vast sums for pacemakers and ICDs "enhanced" with the QuickOpt feature and for QuickOpt procedures that St. Jude knew had no proven utility, and therefore were not medically necessary to treat any condition. Accordingly, St. Jude has knowingly caused multiple false claims to be presented to the federal and state governments.

A. Relator Discovered the Flaws in the Baker Study [redacted]

78. [redacted]

[redacted]

79. [redacted]

80. [redacted] the supposedly strong correlation between QuickOpt and Doppler echocardiography was entirely caused by the modest variability of AVTI within individual patients compared to the large differences in AVTI that occur between patients. Put another way, while a patient's AVTI does change with the pacing interval, the magnitude of the change is dwarfed by differences in AVTI between patients. By comparing the intervals from QuickOpt and Doppler echocardiography against a static measure such as AVTI (*i.e.*, one with low intra-patient variability and high inter-patient variability), the Baker study ensured near-perfect correlation.

81. To illustrate this point, imagine the Baker study had measured the patient's shoe size instead of AVTI. The researchers would find a 100 percent correlation between the patient's shoe size at QuickOpt's suggested delays, at Doppler echocardiography's optimum delays, at default delays, and at random delays. Obviously, the perfect correlation has nothing to do with QuickOpt, because shoe size has nothing to do with one's heartbeat. In this case, the patient's delay intervals will affect his or her AVTI, but only very little compared to how much AVTI varies between patients, hence the correlations of 96 percent instead of 100 percent.

82. [redacted] by comparing AVTIs, the Baker study would necessarily have found the same degree of correlation whether it was using true optimum intervals, fixed default intervals, or randomly selected intervals. Its analysis and conclusions, in other words, were meaningless.

1. QuickOpt's Untested Predictions Could Harm Patients

83. QuickOpt is a potential danger to patients. Because there is no evidence that QuickOpt's predicted intervals are better than ones selected at random, there is a very good chance that some patients who receive QuickOpt optimization are ending up with worse cardiac function than then they would have if their CRT devices had been left at the default intervals. As discussed above, pacing intervals have an acute effect on the heart's performance. CRT has been proven to reduce mortality and morbidity in heart failure patients. But choosing the wrong delay intervals erases that benefit, and increases the odds that the patient will stay unhealthy or even die. As one of the Baker study's authors said in explaining the value of optimization, programming a suboptimal interval into a CRT device is "like running an air conditioner on a hot day with the windows open." For patients suffering serious complications from heart failure, this is not an acceptable result.

84. The CRT device's default settings, while not necessarily the best setting for every patient, are the average best settings for the patient group, based on clinical studies. By functioning to replace these default settings with predicted "optimal" settings, QuickOpt could be choosing settings that are *worse* than the default, possibly making optimization with QuickOpt worse than no optimization at all for some patients. There is no valid clinical evidence showing that QuickOpt is better than choosing randomly-selected delays. In some respects, St. Jude's marketing of QuickOpt is akin to encouraging a patient to discontinue an effective drug in favor of a homemade remedy that promises a miracle cure. [redacted]

[redacted]

2. [redacted]

85. [redacted]

86. [redacted]

[redacted]

[redacted]

88. [redacted]

89. [redacted]

[redacted]

90. [redacted]

[redacted]

[redacted]

91. [redacted]

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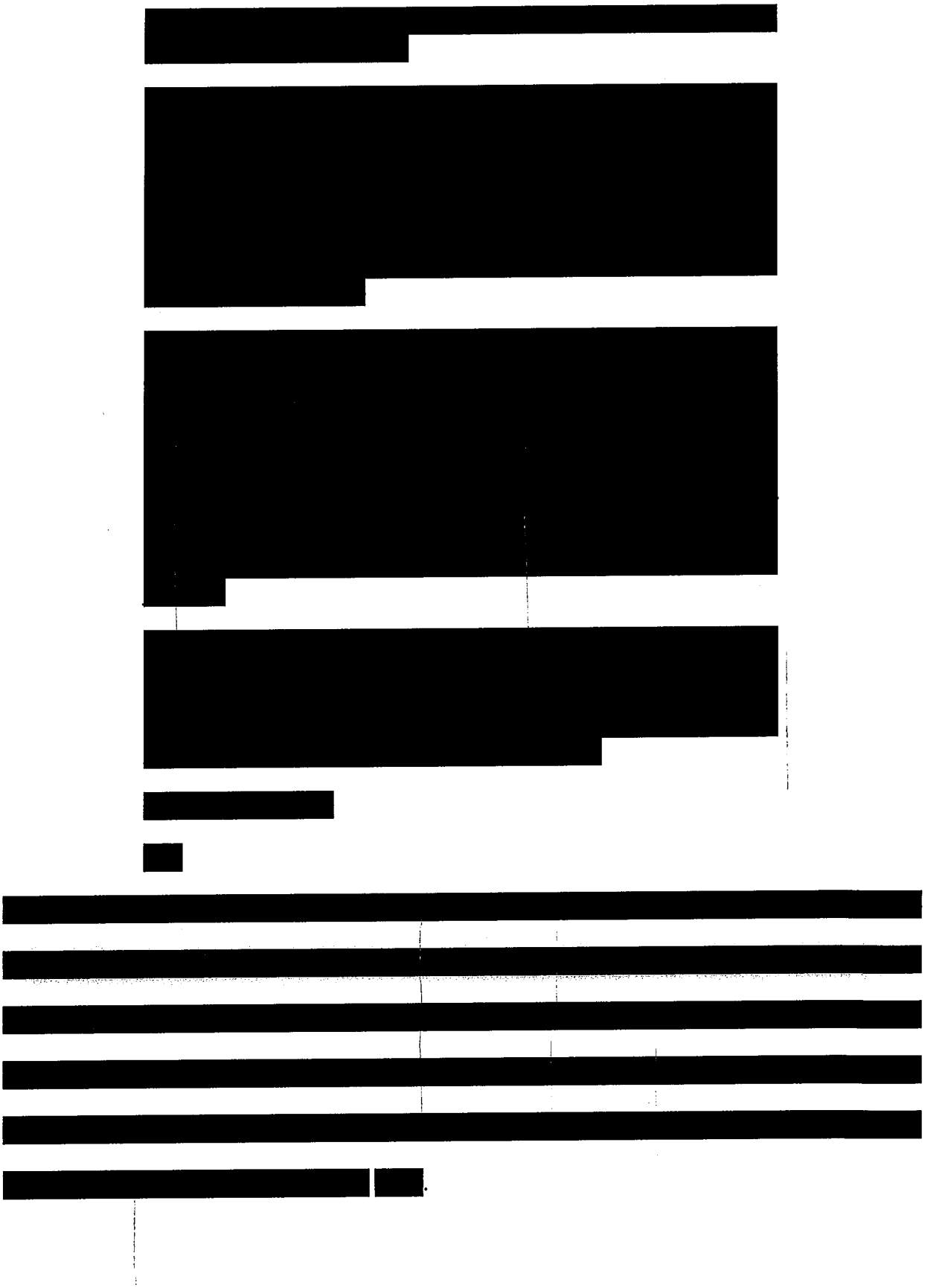

3. [redacted]

92. [redacted]

93. [redacted]

VI. FALSE REPRESENTATIONS MADE BY ST. JUDE IN PROMOTING THE USE OF QUICKOPT

94. [redacted] St. Jude continues to falsely and deceptively promote QuickOpt to physicians as a clinically proven method for optimizing heart rhythm. This promotion occurs in many ways, ranging from visits by St. Jude's salespeople, to claims made in St. Jude's product literature, marketing materials, and website.

1. Promotion Through St. Jude's Sales Representatives

95. The principal way in which St. Jude promotes QuickOpt to physicians is through direct contact by its salespeople. St. Jude's sales representatives aggressively promote QuickOpt as a reason for choosing St. Jude's pacemakers and ICDs over those of its larger competitors, Medtronic and Boston Scientific. Even after St. Jude has received multiple warnings about QuickOpt, its sales representatives continue to tout QuickOpt as a clinically proven optimization method. [redacted]."

2. Deceptive Information in the CRT Device Programmer's Software

96. Second, St. Jude includes information on QuickOpt in the help menus for its Merlin PCS Programmer software. As discussed above, the Merlin is a computer that physicians use to communicate with and program implanted devices. The representations St. Jude makes in the Merlin's software are intended to educate the treating physician about various programming features. Because the representations are incorporated in the programmer itself, they reasonably have a direct impact on the physician's choice of therapy.

97. The "Merlin PCS Help" page for QuickOpt includes basic information on QuickOpt's display window, product warnings, and product notes. It also includes, however, a link to a "[s]ummary of the acute IEGM studies" that established QuickOpt's efficacy.

98. Following the link to Merlin's summary of acute IEGM studies, one will find a detailed summary of the Baker study (and no others). The summary states that the Baker study's primary objective was to identify a correlation of no less than 90% between echocardiography's AVTI and QuickOpt's predicted AVTI. The summary reproduces the Baker study's results, with correlations all exceeding 90%, and concludes:

> In summary, the primary study objectives were met for the PV delay [sensed AV delay], AV delay [paced AV delay], and VV delay determinations. Thus, the IEGM method [QuickOpt] is effective in deriving the optimized PV, AV, and VV delays in comparison to the standard Echo optimization method.

99. St. Jude knows that the Baker study's conclusions are misleading. Nevertheless, St. Jude continues to use the study to assure physicians that QuickOpt is safe and effective, even though it knows the study cannot support that conclusion. Compounding the fraud, St. Jude displays this misleading information on the programmer itself—the immediate tool for administering QuickOpt. The result is that physicians are deceived into performing a procedure on heart failure patients that has no known benefit, instead of using alternative optimization methods that have been proven to be effective and safe. Consequently, Medicare and Medicaid have paid vast sums for these medically unnecessary procedures.

3. Misleading Information on the St. Jude Website

100. St. Jude also markets QuickOpt to physicians by way of false statements displayed on its website. First, St. Jude has published a white paper online entitled "IEGM AV/PV and VV Study: Clinical Update" that reports the ostensibly impressive, but misleading, results of the Baker study. The white paper summarizes the Baker study in detail, concluding: "All endpoints of this study were met. The QuickOpt Timing Cycle Optimization algorithm has shown to be comparable to standard echo-guided methods of timing cycle optimization." As discussed above, St. Jude has ample reason to know this claim is false. By continuing to promote the Baker study and its misleading data, St. Jude is fraudulently inducing physicians to perform QuickOpt procedures (and prescribe St. Jude CRT devices), in the mistaken belief that QuickOpt has beneficial effects.

101. In another webpage, St. Jude claims that QuickOpt "provides a clinically proven 97% correlation to echocardiography, providing the opportunity for optimization of AV delay in

about a minute at every visit." Again, St. Jude has reason to know this claim is misleading. In the same page, St. Jude also reproduces a chart and graphs from the Baker study, even though it has reason to know the data are not trustworthy.

102. In yet another product webpage, St. Jude states that "QuickOpt Timing Cycle Optimization is clinically proven to correlate with more time-consuming echo-based methods." Again, St. Jude has reason to know this is untrue. St. Jude similarly claims on the same page that QuickOpt "has been clinically proven to correlate with echo-based optimization." And, as with the other webpage, St. Jude reproduces charts and graphs displaying the Baker study's discredited data.

103. St. Jude also makes physician "testimonials" about QuickOpt available on its website. One testimonial from a Dr. Eugene Rhim states that "QuickOpt is the only available one-touch CRT optimization algorithm that has been proven to be as effective as echocardiogram-based optimization." In light of what St. Jude knows about the Baker study, this statement is flatly misleading.

VII. IMPACT ON PRIVATE INSURERS

104. The states of California and Illinois have enacted Insurance Fraud Prevention Acts that permit Relator to bring a *qui tam* action to recover for fraudulent claims submitted to *private* insurance companies in those states. *See* Counts III and XI below.

105. Although this Complaint has focused on the impact of defendant's practices on the federal and state governments, these same practices also defraud private insurance companies in the same manner that the practices defraud the federal and state governments.

106. The practices alleged herein are systematic, nationwide practices that defraud private insurance companies that reimburse medical procedures in every state where defendant conducts business, including California and Illinois.

Count I
Federal False Claims Act
31 U.S.C. §§ 3729(a)(1)(A)–(B)

107. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 106 above as though fully set forth herein.

108. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. § 3729, *et seq.*, as amended.

109. By virtue of the acts described above, defendant knowingly presented or caused to be presented, false or fraudulent claims to officers, employees or agents of the United States Government for payment or approval under Medicaid, Medicare and various other government health care programs, within the meaning of 31 U.S.C. § 3729(a)(1)(A).

110. By virtue of the acts described above, defendant knowingly made, used, or caused to be made or used false or fraudulent records and statements, and omitted material facts, to get false and fraudulent claims paid or approved under Medicaid, Medicare and various other government health care programs, within the meaning of 31 U.S.C. § 3729(a)(1)(B).

111. The United States, unaware of the falsity of the records, statements and claims made or caused to be made by the defendant, paid and continues to pay the claims that would not be paid but for defendant's unlawful conduct.

112. By reason of the defendant's acts, the United States has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

113. Additionally, the United States is entitled to the maximum penalty of $11,000 for each and every false and fraudulent claim made and caused to be made by defendant arising from their unlawful conduct as described herein.

Count II
California False Claims Act
Cal Govt Code § 12651(a)(1)-(2)

114. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 106 above as though fully set forth herein.

115. This is a claim for treble damages and penalties under the California False Claims Act.

116. By virtue of the acts described above, defendant knowingly presented or caused to be presented, false or fraudulent claims to the California State Government for payment or approval.

117. By virtue of the acts described above, defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the California State Government to approve and pay such false and fraudulent claims.

118. The California State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendant, paid and continues to pay the claims that would not be paid but for defendant's unlawful conduct.

119. By reason of the defendant's acts, the State of California has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

120. Additionally, the California State Government is entitled to the maximum penalty of $10,000 for each and every violation alleged herein.

Count III
California Insurance Frauds Prevention Act
California Insurance Code § 1871.7

121. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 106 above as though fully set forth herein.

122. This is a claim for treble damages and penalties under the California Insurance Frauds Prevention Act, Cal. Ins. Code § 1871.7, as amended (referred to in this Count as "the Act"). The Act provides for civil recoveries against persons who violate the provisions of the Act or the provisions of California Penal Code sections 549 or 550, including recovery of up to three times the amount of any fraudulent insurance claims, and fines of between $5,000 and $10,000 for each such claim. Cal. Ins. Code § 1871.7(b).

123. Subsection (e) of Cal. Ins. Code § 1871.7 provides for a *qui tam* civil action in order to create incentives for private individuals who are aware of fraud against insurers to help disclose and prosecute the fraud. Cal. Ins. Code § 1871.1(e). The *qui tam* provision was patterned after the Federal False Claims Act, 31 U.S.C. §§ 3729–32, and the California False Claims Act, Cal. Gov't Code §§ 12650 *et seq.*

124. Subsection (b) of Cal. Ins. Code § 1871.7 provides for civil recoveries against persons who violate the provisions of Penal Code sections 549 or 550. Section 550 of the Penal Code prohibits the following activities, among others:

> (a) It is unlawful to do any of the following, or to aid, abet, solicit, or conspire with any person to do any of the following:
>
> * * * * * *
>
> (5) Knowingly prepare, make, or subscribe any writing, with the intent to present or use it, or to allow it to be presented, in support of any false or fraudulent claim.
>
> (6) Knowingly make or cause to be made any false or fraudulent claim for payment of a health care benefit.

* * * * * *

(b) It is unlawful to do, or to knowingly assist or conspire with any person to do, any of the following:

(1) Present or cause to be presented any written or oral statement as part of, or in support of or opposition to, a claim for payment or other benefit pursuant to an insurance policy, knowing that the statement contains any false or misleading information concerning any material fact.

(2) Prepare or make any written or oral statement that is intended to be presented to any insurer or any insurance claimant in connection with, or in support of or opposition to, any claim or payment or other benefit pursuant to an insurance policy, knowing that the statement contains any false or misleading information concerning any material fact.

(3) Conceal, or knowingly fail to disclose the occurrence of, an event that affects any person's initial or continued right or entitlement to any insurance benefit or payment, or the amount of any benefit or payment to which the person is entitled.

Cal. Penal Code § 550.

125. By virtue of the acts described in this Complaint, defendant knowingly presented or caused to be presented, false or fraudulent claims for health care benefits, in violation of Penal Code § 550(a).

126. By virtue of the acts described in this Complaint, defendant also concealed and/or failed to disclose information that would have affected the rights of pharmacies to receive reimbursement for prescriptions, in violation of Penal Code § 550(b).

127. Each claim for reimbursement that was inflated as a result of defendant's illegal practices represents a false or fraudulent record or statement, and a false or fraudulent claim for payment.

128. Private insurers, unaware of the falsity of the records, statements and claims made or caused to be made by defendant, paid and continue to pay the claims that would not be paid but for defendant's unlawful conduct.

129. The California State Government is entitled to receive three times the amount of each claim for compensation submitted in violation of Cal. Ins. Code § 1871.7. Additionally, the California State Government is entitled to the maximum penalty of $10,000 for each and every violation alleged herein.

Count IV
Connecticut False Claims Act
Conn. Publ Law 09-05

130. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 106 above as though fully set forth herein.

131. This is a claim for treble damages and penalties under the Connecticut False Claims And Reporting Act.

132. By virtue of the acts described above, defendant knowingly presented or caused to be presented, false or fraudulent claims to the Connecticut State Government for payment or approval.

133. By virtue of the acts described above, defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Connecticut State Government to approve and pay such false and fraudulent claims.

134. The Connecticut State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendant, paid and continues to pay the claims that would not be paid but for defendant's unlawful conduct.

135. By reason of the defendant's acts, the State of Connecticut has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

136. Additionally, the Connecticut State Government is entitled to the maximum penalty of $10,000 for each and every violation alleged herein.

Count V
Delaware False Claims And Reporting Act
6 Del C. § 1201(a)(1)-(3)

137. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 106 above as though fully set forth herein.

138. This is a claim for treble damages and penalties under the Delaware False Claims And Reporting Act.

139. By virtue of the acts described above, defendant knowingly presented or caused to be presented, false or fraudulent claims to the Delaware State Government for payment or approval.

140. By virtue of the acts described above, defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Delaware State Government to approve and pay such false and fraudulent claims.

141. The Delaware State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendant, paid and continues to pay the claims that would not be paid but for defendant's unlawful conduct.

142. By reason of the defendant's acts, the State of Delaware has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

143. Additionally, the Delaware State Government is entitled to the maximum penalty of $11,000 for each and every violation alleged herein.

Count VI
District of Columbia Procurement Reform Amendment Act
D.C. Code Ann. § 1-1188.14(a)(1)–(2)

144. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1 through 106 of this Complaint.

145. This is a claim for treble damages and penalties under the District of Columbia Procurement Reform Amendment Act.

146. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the District of Columbia Government for payment or approval.

147. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the District of Columbia Government to approve and pay such false and fraudulent claims.

148. The District of Columbia Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' defective laboratory tests, unnecessary treatments and surgeries, and/or illegal inducements and business practices.

149. By reason of the defendants' acts, the District of Columbia has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

150. The District of Columbia is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

Count VII
Florida False Claims Act
Fla. Stat. Ann. § 68.082(2)

151. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 106 above as though fully set forth herein.

152. This is a claim for treble damages and penalties under the Florida False Claims Act.

153. By virtue of the acts described above, defendant knowingly presented or caused to be presented, false or fraudulent claims to the Florida State Government for payment or approval.

154. By virtue of the acts described above, defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Florida State Government to approve and pay such false and fraudulent claims.

155. The Florida State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendant, paid and continues to pay the claims that would not be paid but for defendant's unlawful conduct.

156. By reason of the defendant's acts, the State of Florida has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

157. Additionally, the Florida State Government is entitled to the maximum penalty of $10,000 for each and every violation alleged herein.

Count VIII
Georgia False Claims Act
Ga. Code Ann. § 49-4-168

158. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 106 above as though fully set forth herein.

159. This is a claim for treble damages and penalties under the Georgia False Claims Act.

160. By virtue of the acts described above, defendant knowingly presented or caused to be presented, false or fraudulent claims to the Georgia State Government for payment or approval.

161. By virtue of the acts described above, defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Georgia State Government to approve and pay such false and fraudulent claims.

162. The Georgia State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendant, paid and continues to pay the claims that would not be paid but for defendant's unlawful conduct.

163. By reason of the defendant's acts, the State of Georgia has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

164. Additionally, the Georgia State Government is entitled to the maximum penalty of $11,000 for each and every violation alleged herein.

Count IX
Hawaii False Claims Act
Haw. Rev. Stat. § 661-21(a)

165. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 106 above as though fully set forth herein.

166. This is a claim for treble damages and penalties under the Hawaii False Claims Act.

167. By virtue of the acts described above, defendant knowingly presented or caused to be presented, false or fraudulent claims to the Hawaii State Government for payment or approval.

168. By virtue of the acts described above, defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Hawaii State Government to approve and pay such false and fraudulent claims.

169. The Hawaii State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendant, paid and continues to pay the claims that would not be paid but for defendant's unlawful conduct.

170. By reason of the defendant's acts, the State of Hawaii has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

171. Additionally, the Hawaii State Government is entitled to the maximum penalty of $10,000 for each and every violation alleged herein.

Count X
Illinois Whistleblower Reward And Protection Act
740 Ill. Comp. Stat. § 175/3(a)(1)-(3)

172. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 106 above as though fully set forth herein.

173. This is a claim for treble damages and penalties under the Illinois Whistleblower Reward And Protection Act.

174. By virtue of the acts described above, defendant knowingly presented or caused to be presented, false or fraudulent claims to the Illinois State Government for payment or approval.

175. By virtue of the acts described above, defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Illinois State Government to approve and pay such false and fraudulent claims.

176. The Illinois State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendant, paid and continues to pay the claims that would not be paid but for defendant's unlawful conduct.

177. By reason of the defendant's acts, the State of Illinois has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

178. Additionally, the Illinois State Government is entitled to the maximum penalty of $10,000 for each and every violation alleged herein.

Count XI
Illinois Insurance Claims Frauds Prevention Act
740 Ill. Comp. Stat. § 92

179. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 106 above as though fully set forth herein.

180. This is a claim for treble damages and penalties under the Illinois Insurance Claims Fraud Prevention Act, 740 Ill. Comp. Stat. § 92.

181. Subsection 5(b) of the Illinois Insurance Claims Fraud Prevention Act provides:

> A person who violates any provision of this Act or Article 46 of the Criminal Code of 1961 shall be subject, in addition to any other penalties that may be prescribed by law, to a civil penalty of not less than $5,000 nor more than $10,000, plus an assessment of not more than 3 times the amount of each claim for compensation under a contract of insurance.

182. Article 46 of the Illinois Criminal Code, referenced in the above-quoted section, provides criminal penalties for any person who commits the offense of insurance fraud, defined in the statute as follows:

> (a) A person commits the offense of insurance fraud when he or she knowingly obtains, attempts to obtain, or causes to be obtained, by deception, control over the property of an insurance company or self-insured entity by the making of a false claim or by causing a false claim to be made on any policy of insurance issued by an insurance company . . . .

720 Ill. Comp. Stat. § 5/46-1(a).

183. Subsection 15(a) of the Illinois Insurance Claims Fraud Prevention Act provides for a qui tam civil action in order to create incentives for private individuals to prosecute violations of the statute. Subsection 15(a) provides: "An interested person, including an insurer, may bring a civil action for a violation of this Act for the person and for the State of Illinois. The action shall be brought in the name of the State." 740 Ill. Comp. Stat. § 92/15(a).

184. By virtue of the conduct described in this Complaint, defendant committed the following acts, or aided and abetted the commission of the following acts, in violation of the Illinois Insurance Claims Fraud Prevention Act: knowingly obtained, attempted to obtain, and caused to be obtained, by deception, control over the property of an insurance company or self-insured entity by the making of a false claim and by causing a false claim to be made on a policy of insurance issued by an insurance company, in violation of 740 Ill. Comp. Stat. § 92/5(b) and 720 Ill. Comp. Stat. § 5/46-1(a).

185. As a result of such conduct, defendant has received illegal profits to which it was not entitled, at the expense of insurers and at the expense of the People of the State of Illinois, in substantial amount to be determined at trial.

186. The Illinois State Government is entitled to receive three times the amount of each claim for compensation submitted by defendant in violation of 740 Ill. Comp. Stat. § 92. Additionally, the Illinois State Government is entitled to the maximum penalty of $10,000 for each and every violation alleged herein.

Count XII
Indiana False Claims And Whistleblower Protection Act
IC 5-11-5.5-2(b)(1) and (2)

187. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 106 above as though fully set forth herein.

188. This is a claim for treble damages and penalties under the Indiana False Claims And Whistleblower Protection Act.

189. By virtue of the acts described above, defendant knowingly presented or caused to be presented, false or fraudulent claims to the Indiana State Government for payment or approval.

190. By virtue of the acts described above, defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Indiana State Government to approve and pay such false and fraudulent claims.

191. The Indiana State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendant, paid and continues to pay the claims that would not be paid but for defendant's unlawful conduct.

192. By reason of the defendant's acts, the State of Indiana has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

193. Additionally, the Indiana State Government is entitled to a civil penalty of at least $5,000 for each and every violation alleged herein.

Count XIII
Louisiana Medical Assistance Programs Integrity Law
La. Rev. Stat. § 437 *et seq.*

194. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 106 above as though fully set forth herein.

195. This is a claim for treble damages and penalties under the Louisiana Medical Assistance Programs Integrity Law.

196. By virtue of the acts described above, defendant knowingly presented or caused to be presented, false or fraudulent claims to the Louisiana State Government for payment or approval.

197. By virtue of the acts described above, defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Louisiana State Government to approve and pay such false and fraudulent claims.

198. The Louisiana State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendant, paid and continues to pay the claims that would not be paid but for defendant's unlawful conduct.

199. By reason of the defendant's acts, the State of Louisiana has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

200. Additionally, the Louisiana State Government is entitled to the maximum penalty of $10,000 for each and every violation alleged herein.

Count XIV
Massachusetts False Claims Law
Mass. Gen. Laws ch. 12 § 5B(1)-(3)

201. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 106 above as though fully set forth herein.

202. This is a claim for treble damages and penalties under the Massachusetts False Claims Law.

203. By virtue of the acts described above, defendant knowingly presented or caused to be presented, false or fraudulent claims to the Massachusetts State Government for payment or approval.

204. By virtue of the acts described above, defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Massachusetts State Government to approve and pay such false and fraudulent claims.

205. The Massachusetts State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendant, paid and continues to pay the claims that would not be paid but for defendant's unlawful conduct.

206. By reason of the defendant's acts, the State of Massachusetts has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

207. Additionally, the Massachusetts State Government is entitled to the maximum penalty of $10,000 for each and every violation alleged herein.

Count XV
Michigan Medicaid False Claims Act
Mich. Comp. Laws. § 400.601

208. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 106 above as though fully set forth herein.

209. This is a claim for treble damages and penalties under the Michigan Medicaid False Claims Act.

210. By virtue of the acts described above, defendant knowingly presented or caused to be presented, false or fraudulent claims to the Michigan State Government for payment or approval.

211. By virtue of the acts described above, defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Michigan State Government to approve and pay such false and fraudulent claims.

212. The Michigan State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendant, paid and continues to pay the claims that would not be paid but for defendant's unlawful conduct.

213. By reason of the defendant's acts, the State of Michigan has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

214. Additionally, the Michigan State Government is entitled to the maximum penalty of $10,000 for each and every violation alleged herein.

Count XVI
Montana False Claims Act
Mont. Code Ann. § 17-8-401 *et seq.*

215. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 106 above as though fully set forth herein.

216. This is a claim for treble damages and penalties under the Montana False Claims Act.

217. By virtue of the acts described above, defendant knowingly presented or caused to be presented, false or fraudulent claims to the Montana State Government for payment or approval.

218. By virtue of the acts described above, defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Montana State Government to approve and pay such false and fraudulent claims.

219. The Montana State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendant, paid and continues to pay the claims that would not be paid but for defendant's unlawful conduct.

220. By reason of the defendant's acts, the State of Montana has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

221. Additionally, the Montana State Government is entitled to the maximum penalty of $10,000 for each and every violation alleged herein.

Count XVII
Nevada False Claims Act
Nev. Rev. Stat. Ann. § 357.040(1)(a)-(c)

222. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 106 above as though fully set forth herein.

223. This is a claim for treble damages and penalties under the Nevada False Claims Act.

224. By virtue of the acts described above, defendant knowingly presented or caused to be presented, false or fraudulent claims to the Nevada State Government for payment or approval.

225. By virtue of the acts described above, defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Nevada State Government to approve and pay such false and fraudulent claims.

226. The Nevada State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendant, paid and continues to pay the claims that would not be paid but for defendant's unlawful conduct.

227. By reason of the defendant's acts, the State of Nevada has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

228. Additionally, the Nevada State Government is entitled to the maximum penalty of $10,000 for each and every violation alleged herein.

Count XVIII
New Hampshire False Claims Act
N.H. Rev. Stat. Ann. § 167:61-b(I)(a)-(c)

229. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 106 above as though fully set forth herein.

230. This is a claim for treble damages and penalties under the New Hampshire False Claims Act.

231. By virtue of the acts described above, defendant knowingly presented or caused to be presented, false or fraudulent claims to the New Hampshire State Government for payment or approval.

232. By virtue of the acts described above, defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the New Hampshire State Government to approve and pay such false and fraudulent claims.

233. The New Hampshire State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendant, paid and continues to pay the claims that would not be paid but for defendant's unlawful conduct.

234. By reason of the defendant's acts, the State of New Hampshire has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

235. Additionally, the New Hampshire State Government is entitled to the maximum penalty of $10,000 for each and every violation alleged herein.

Count XIX
New Jersey False Claims Act
N.J. Stat. § 2A:32C-1

236. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 106 above as though fully set forth herein.

237. This is a claim for treble damages and penalties under the New Jersey False Claims Act.

238. By virtue of the acts described above, defendant knowingly presented or caused to be presented, false or fraudulent claims to the New Jersey State Government for payment or approval.

239. By virtue of the acts described above, defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the New Jersey State Government to approve and pay such false and fraudulent claims.

240. The New Jersey State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendant, paid and continues to pay the claims that would not be paid but for defendant's unlawful conduct.

241. By reason of the defendant's acts, the State of New Jersey has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

242. Additionally, the New Jersey State Government is entitled to the maximum penalty of $10,000 for each and every violation alleged herein.

Count XX
New Mexico Medicaid False Claims Act, N.M. Stat. Ann. § 27-14-1 *et seq.* and New Mexico Fraud Against Taxpayers Act, N.M. Stat. Ann. § 44-9-1 et seq

243. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 106 above as though fully set forth herein.

244. This is a claim for treble damages and penalties under the New Mexico Medicaid False Claims Act and the New Mexico Fraud Against Taxpayers Act.

245. By virtue of the acts described above, defendant knowingly presented or caused to be presented, false or fraudulent claims to the New Mexico State Government for payment or approval.

246. By virtue of the acts described above, defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the New Mexico State Government to approve and pay such false and fraudulent claims.

247. The New Mexico State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendant, paid and continues to pay the claims that would not be paid but for defendant's unlawful conduct.

248. By reason of the defendant's acts, the State of New Mexico has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

249. Additionally, the New Mexico State Government is entitled to the maximum civil penalty of $10,000 for each and every violation alleged herein.

Count XXI
New York False Claims Act
N.Y. State Fin. § 187

250. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 106 above as though fully set forth herein.

251. This is a claim for treble damages and penalties under the New York False Claims Act.

252. By virtue of the acts described above, defendant knowingly presented or caused to be presented, false or fraudulent claims to the New York State Government for payment or approval.

253. By virtue of the acts described above, defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the New York State Government to approve and pay such false and fraudulent claims.

254. The New York State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendant, paid and continues to pay the claims that would not be paid but for defendant's unlawful conduct.

255. By reason of the defendant's acts, the State of New York has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

256. Additionally, the New York State Government is entitled to the maximum penalty of $12,000 for each and every violation alleged herein.

Count XXII
North Carolina False Claims Act
N.C. Gen. Stat. § 1-605 et seq.

257. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 106 above as though fully set forth herein.

258. This is a claim for treble damages and penalties under the North Carolina False Claims Act.

259. By virtue of the acts described above, defendant knowingly presented or caused to be presented, false or fraudulent claims to the North Carolina State Government for payment or approval.

260. By virtue of the acts described above, defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the North Carolina State Government to approve and pay such false and fraudulent claims.

261. The North Carolina State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendant, paid and continues to pay the claims that would not be paid but for defendant's unlawful conduct.

262. By reason of the defendant's acts, the State of North Carolina has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

263. Additionally, the North Carolina State Government is entitled to the maximum penalty of $11,000 for each and every violation alleged herein.

Count XXIII
Oklahoma Medicaid False Claims Act
63 Okl. St. § 5053

264. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 106 above as though fully set forth herein.

265. This is a claim for treble damages and penalties under the Oklahoma Medicaid False Claims Act.

266. By virtue of the acts described above, defendant knowingly presented or caused to be presented, false or fraudulent claims to the Oklahoma State Government for payment or approval.

267. By virtue of the acts described above, defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Oklahoma State Government to approve and pay such false and fraudulent claims.

268. The Oklahoma State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendant, paid and continues to pay the claims that would not be paid but for defendant's unlawful conduct.

269. By reason of the defendant's acts, the State of Oklahoma has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

270. Additionally, the Oklahoma State Government is entitled to the maximum civil penalty of $10,000 for each and every violation alleged herein.

Count XXIV
Rhode Island False Claims Act
R.I. Gen. Laws § 9-1.1-1

271. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 106 above as though fully set forth herein.

272. This is a claim for treble damages and penalties under the Rhode Island False Claims Act.

273. By virtue of the acts described above, defendant knowingly presented or caused to be presented, false or fraudulent claims to the Rhode Island State Government for payment or approval.

274. By virtue of the acts described above, defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Rhode Island State Government to approve and pay such false and fraudulent claims.

275. The Rhode Island State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendant, paid and continues to pay the claims that would not be paid but for defendant's unlawful conduct.

276. By reason of the defendant's acts, the State of Rhode Island has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

277. Additionally, the Rhode Island State Government is entitled to civil penalties for each and every violation alleged herein.

Count XXV
Tennessee False Claims Act and Medicaid False Claims Act
Tenn. Code Ann. §§ 4-18-103(a) and 71-5-182(a)(1)

278. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 106 above as though fully set forth herein.

279. This is a claim for treble damages and penalties under the Tennessee False Claims Act and Tennessee Medicaid False Claims Act.

280. By virtue of the acts described above, defendant knowingly presented or caused to be presented, false or fraudulent claims to the Tennessee State Government for payment or approval.

281. By virtue of the acts described above, defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Tennessee State Government to approve and pay such false and fraudulent claims.

282. The Tennessee State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendant, paid and continues to pay the claims that would not be paid but for defendant's unlawful conduct.

283. By reason of the defendant's acts, the State of Tennessee has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

284. Additionally, the Tennessee State Government is entitled to the maximum penalty of $10,000 for each and every violation alleged herein.

Count XXVI
Texas Medicaid Fraud Prevention Law
Tex. Hum. Res. Code Ann. § 36.002

285. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 106 above as though fully set forth herein.

286. This is a claim for treble damages and penalties under the Texas Medicaid Fraud Prevention Law.

287. By virtue of the acts described above, defendant knowingly presented or caused to be presented, false or fraudulent claims to the Texas State Government for payment or approval.

288. By virtue of the acts described above, defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Texas State Government to approve and pay such false and fraudulent claims.

289. The Texas State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendant, paid and continues to pay the claims that would not be paid but for defendant's unlawful conduct.

290. By reason of the defendant's acts, the State of Texas has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

291. Additionally, the Texas State Government is entitled to the maximum penalty of $10,000 for each and every violation alleged herein.

Count XXVII
Virginia Fraud Against Taxpayers Act
Va. Code Ann. § 8.01-216.3(a)(1)-(3)

292. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 106 above as though fully set forth herein.

293. This is a claim for treble damages and penalties under the Virginia Fraud Against Taxpayers Act.

294. By virtue of the acts described above, defendant knowingly presented or caused to be presented, false or fraudulent claims to the Virginia State Government for payment or approval.

295. By virtue of the acts described above, defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Virginia State Government to approve and pay such false and fraudulent claims.

296. The Virginia State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendant, paid and continues to pay the claims that would not be paid but for defendant's unlawful conduct.

297. By reason of the defendant's acts, the State of Virginia has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

298. Additionally, the Virginia State Government is entitled to the maximum penalty of $10,000 for each and every violation alleged herein.

Count XXVIII
Wisconsin False Claims For Medical Assistance Act
Wis. Stat § 20.931 *et seq.*

299. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 106 above as though fully set forth herein.

300. This is a claim for treble damages and penalties under the Wisconsin False Claims For Medical Assistance Act.

301. By virtue of the acts described above, defendant knowingly presented or caused to be presented, false or fraudulent claims to the Wisconsin Government for payment or approval.

302. By virtue of the acts described above, defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the State of Wisconsin to approve and pay such false and fraudulent claims.

303. The State of Wisconsin, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendant, paid and continues to pay the claims that would not be paid but for defendant's unlawful conduct.

304. By reason of the defendant's acts, the State of Wisconsin has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

305. Additionally, the State of Wisconsin is entitled to the maximum penalty of $10,000 for each and every violation alleged herein.

Prayer

WHEREFORE, Relator prays for judgment against the defendant as follows:

1. that defendant cease and desist from violating 31 U.S.C. § 3729 *et seq.*, and the counterpart provisions of the state statutes set forth above;

2. that this Court enter judgment against defendant in an amount equal to three times the amount of damages the United States has sustained because of defendant's actions, plus a civil penalty of not less than $5,000 and not more than $11,000 for each violation of 31 U.S.C. § 3729;

3. that this Court enter judgment against defendant in an amount equal to three times the amount of damages the State of California has sustained because of defendant's actions, plus a civil penalty of $10,000 for each violation of Cal. Govt. Code § 12651(a);

4. that this Court enter judgment against defendant in an amount equal to three times the amount of each claim for compensation submitted by defendant in violation of Cal. Ins. Code

§ 1871.7(b), plus a civil penalty of $10,000 for each violation of Cal. Ins. Code § 1871.7(b);

5. that this Court enter judgment against defendant in an amount equal to three times the amount of damages the State of Connecticut has sustained because of defendant's actions, plus a civil penalty of $10,000 for each violation of Conn. Pub. Law 09-05;

6. that this Court enter judgment against defendant in an amount equal to three times the amount of damages the State of Delaware has sustained because of defendant's actions, plus a civil penalty of $11,000 for each violation of 6 Del. C. § 1201(a);

7. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the District of Columbia has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of D.C. Code Ann. § 1-1188.14(a)(1)–(2);

8. that this Court enter judgment against defendant in an amount equal to three times the amount of damages the State of Florida has sustained because of defendant's actions, plus a civil penalty of $10,000 for each violation of Fla. Stat. Ann. § 68.082(2);

9. that this Court enter judgment against defendant in an amount equal to three times the amount of damages the State of Georgia has sustained because of defendant's actions, plus a civil penalty of $10,000 for each violation of Georgia Code Ann. § 49-4-168;

10. that this Court enter judgment against defendant in an amount equal to three times the amount of damages the State of Hawaii has sustained because of defendant's actions, plus a civil penalty of $10,000 for each violation of Haw. Rev. Stat. § 661-21(a);

11. that this Court enter judgment against defendant in an amount equal to three times the amount of damages the State of Illinois has sustained because of defendant's actions, plus a civil penalty of $10,000 for each violation of 740 Ill. Comp. Stat. § 175/3(a);

12. that this Court enter judgment against defendant in an amount equal to three times the amount of each claim for compensation submitted by defendant in violation of 740 Ill. Comp. Stat. § 92, plus a civil penalty of $10,000 for each violation of 740 Ill. Comp. Stat. § 92;

13. that this Court enter judgment against defendant in an amount equal to three times the amount of damages the State of Indiana has sustained because of defendant's actions, plus a civil penalty of $10,000 for each violation of Ind. Code § 5-11-5.5 *et seq.*;

14. that this Court enter judgment against defendant in an amount equal to three times the amount of damages the State of Louisiana has sustained because of defendant's actions, plus a civil penalty of $10,000 for each violation of La. Rev. Stat. § 437 *et seq.*;

15. that this Court enter judgment against defendant in an amount equal to three times the amount of damages the State of Massachusetts has sustained because of defendant's actions, plus a civil penalty of $10,000 for each violation of Mass. Gen. L. Ch. 12 § 5B *et seq.*;

16. that this Court enter judgment against defendant in an amount equal to three times the amount of damages the State of Michigan has sustained because of defendant's actions, plus a civil penalty of $10,000 for each violation of Mich. Comp. Laws § 400.601 *et seq.*;

17. that this Court enter judgment against defendant in an amount equal to three times the amount of damages the State of Montana has sustained because of defendant's actions, plus a civil penalty of $10,000 for each violation of Mont. Code Ann. § 17-8-401 *et seq.*;

18. that this Court enter judgment against defendant in an amount equal to three times the amount of damages the State of Nevada has sustained because of defendant's actions, plus a civil penalty of $10,000 for each violation of Nev. Rev. Stat. Ann. § 357.040(1);

19. that this Court enter judgment against defendant in an amount equal to three times the amount of damages the State of New Hampshire has sustained because of defendant's

actions, plus civil penalties for each violation of N.H. Rev. Stat. Ann. § 167:61-b(I);

20. that this Court enter judgment against defendant in an amount equal to three times the amount of damages the State of New Jersey has sustained because of defendant's actions, plus civil penalties for each violation of N.J. Stat. § 2A:32C-1 *et seq.*;

21. that this Court enter judgment against defendant in an amount equal to three times the amount of damages the State of New Mexico has sustained because of defendant's actions, plus civil penalties for each violation of N.M. Stat. Ann. § 27-14-4 *et seq.* and N.M. Stat. Ann. § 44-9-1 *et seq.*;

22. that this Court enter judgment against defendant in an amount equal to three times the amount of damages the State of New York has sustained because of defendant's actions, plus civil penalties for each violation of N.Y. State Fin. § 187 *et seq.*;

23. that this Court enter judgment against defendant in an amount equal to three times the amount of damages the State of North Carolina has sustained because of defendant's actions, plus a civil penalty of $11,000 for each violation of N.C. Gen. Stat. § 1-605 *et seq*;

24. that this Court enter judgment against defendant in an amount equal to three times the amount of damages the State of Oklahoma has sustained because of defendant's actions, plus civil penalties for each violation of 63 Okla. St. § 5053 *et seq.*;

25. that this Court enter judgment against defendant in an amount equal to three times the amount of damages the State of Rhode Island has sustained because of defendant's actions, plus civil penalties for each violation of R.I. Gen. Laws § 9-1.1-1 *et seq.*;

26. that this Court enter judgment against defendant in an amount equal to three times the amount of damages the State of Tennessee has sustained because of defendant's actions, plus a civil penalty of $10,000 for each violation of Tenn. Code Ann. §§ 4-18-103(a) and 71-5-

182(a)(1);

27. that this Court enter judgment against defendant in an amount equal to three times the amount of damages the State of Texas has sustained because of defendant's actions, plus a civil penalty of $10,000 for each violation of Tex. Hum. Res. Code Ann. § 36.002;

28. that this Court enter judgment against defendant in an amount equal to three times the amount of damages the State of Virginia has sustained because of defendant's actions, plus a civil penalty of $10,000 for each violation of Va. Code Ann. § 8.01-216.3(a);

29. that this Court enter judgment against defendant in an amount equal to three times the amount of damages the State of Wisconsin has sustained because of defendant's actions, plus a civil penalty of $10,000 for each violation of the Wis. Stat. § 20.931 *et seq.*;

30. that Relator be awarded the maximum amount allowed pursuant to § 3730(d) of the False Claims Act, and the equivalent provisions of the state statutes set forth above;

31. that Relator be awarded all costs of this action, including attorneys' fees and expenses; and

32. that Relator recover such other relief as the Court deems just and proper.

Demand for Jury Trial

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Relator hereby demands a trial by jury.

Dated: May ___, 2010

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By: _____

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Dated: May 21, 2010

Attorneys for *Qui Tam* Plaintiff [redacted]